REMARKS

Status of the Claims

Claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42, 43, 46, 49, 50 and 52-58 are in the application.

Claims 1, 6, 12, 17, 33, 46, 49, 53, 54 and 56 were rejected.

Claims 4, 7, 9-11, 15, 18, 33, 36, 42, 43, 46, 49, 50, 52 and 55-58 are objected to.

Claims 1, 7, 12, 33, 46, 49 and 56 have been amended.

Upon entry of this amendment, claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42, 43, 46, 49, 50 and 52-58 will be pending.

Summary of the Amendment

Claims 1, 7, 12, 33, 46, 49 and 56 have been amended to delete reference to ICAM-1.

Claim 7 has been additionally amended to be written in independent form as an independent method claim.

No new matter has been added.

Claim Rejection Under 35 U.S.C. § 102

Claims 1, 6, 12, 17, and 53-54 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,417,328 (7/9/02), hereafter referred to as Alnemri.

The basis for the rejection is the Office's assertion that Alnemri discloses a pyrogen free composition because the reference indicates that the composition be sterile and contain no other marterial. (Page 3 of Official Action). Applicant respectfully urges that one skilled in the arty reading Alnemri would not expect that the composition in question is pyrogen free. Sterility and the absence of pyrogens are distinct physical conditions. In the drug industry, injectables for human use are required to be both sterile and pyrogen free whereas sterile laboratory reagents are

not prepared using the expensive and resource consuming methodology required for pyrogens to be absent. One skilled in the art knows and recognizes this. In reading Alnemri's description of the compositions that include genes encoding DR5 and pathogen antigens, one skilled in the art would not view the reference to the compositions as being pyrogen free.

Attached hereto is an excerpt fron the r US FDA's online guidelines referring to endotoxin testing. It notes that distillation and reverse osmosis are the most common ways to remove pyrogens from water while physical components are either rinsed with pyrogen free water or dry heat sterilized at high temperature. Laboratory materials are not prepared with this level of purity. Alnemri's reference to compositions which only contain nucleic acid and saline is not teaching that pyrogen contaminants are removed, art least when discussing compositions which contain DR5 and pathogen antigen coding sequences. Pharmaceutical grade material intended for injection are required to be pyrogen free and the manufacture of such materials is therefore performed to ensure of pyrogens. Such extraordinary procedures are not undertaken with materials used in rodent studies.

In view of the foregoing, Applicants respectfully request that the rejections of claims 1, 6, 12, 17, 53 and 54 under 35 U.S.C. § 102(e) as being anticipated by Alnemri be withdrawn.

Claim Rejection Under 35 U.S.C. § 103

Alnemri and Wolff

Claims 1, 6, 12 17 and 53-54 under 35 U.S.C. 103(a) have been rejected as being unpatentable over U.S. Patent No. 6,417,328 (7/9/02), hereafter referred to as Alnemri, in view of U.S. Patent No. 5,693,622 (12/2/97), hereinafter referred to as Wolff..

The Office maintains that one skilled in the art would have a reasonable expectation that plasmid isolated by Alnemri following the teachings of Wolfe would be pyrogen free. Applicants respectfully disagree.

Produce a pyrogen free composition requires absence or removal of pyrogens from all glassware, tubes, caps, and sterile saline solution. To produce such a degree of contaminant free

conditions requires a level of proactivity that is not undertaken for the reagents taught in Alnemri and it is not reasonable to assume that such a level of purity would be intentionally or unintentionally achieved based upon the disclosure or Alnemri in combination with Wolff. Production of pyrogen free compositions according to the claims would only occur if the material was going to be injected as a pharmaceutical. The compositions in Alnemri which comprise nucleic acid sequences that encode pathogen antigens and DR5 are not intended to be used as pharmaceuticals. .

In view of the foregoing, Applicants respectfully request that the rejections of claims 1, 6, 12, 17, 53 and 54 under 35 U.S.C. § 103(a) as being obvious over the combination of Alnemri and Wolff be withdrawn.

Webster and Coplan

Claims 1, 6, 33, 46, 49 and 56 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,916,879, hereafter referred to as Webster, in view of U.S. Patent No. 5,990,301, hereinafter referred to as Coplan..

Webster discloses pplasmids for use as vaccines that comprise coding sequences for a combination of influenza A antigen and ICAM-1. Coplan teaches production of material using methodology that removes contaminants including endotoxins.

Applicants have deleted ICAM-1 from the claims and the rejection is moot.

Claim Objections

Claims 4, 7, 9-11, 15, 18 and 42-53 are objected to as being dependent upon a rejected base claim, but would be allowable based on the elected species of DR5 as the immunomodulating protein if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants have deleted reference to ICAM-1. As amended, the generic claims are allowable and the objection to claims 4, 7, 9-11, 15, 18 and 42-53 are moot.

Conclusion

Claims 1, 4, 6, 7, 9-12, 15, 17, 18, 33, 36, 42, 43, 46, 49, 50 and 52-58 are in condition for allowance. A notice of allowance is earnestly solicited. Applicants invite the Examiner to contact the undersigned at 610.640.7855 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully submitted,

/Mark DeLuca, Reg. No. 33,229/
Mark DeLuca
Registration No. 33,229

Dated: March 15, 2011
PEPPER HAMILTON, LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183
Telephone: 610-640-7855
Facsimile: 267-430-7635